

PRODUCT SPECIFICATIONS SHEET
WORLD/GMP GRADE
ETHYL ACETATE
MEETS REAGENT ACS/USP/NF/EP/BP GRADE MONOGRAPHS
 With USP<232>, EMA and ICH Q3D Test Results

Main Catalog #: 330WORLD-Size Code*

*Individual package sizes have unique size codes

Manufactured in compliance with cGMP

PRODUCT SPECIFICATIONS	MONO GRAPH	LIMITS	TYPICAL RESULT
Assay (corrected for water)	ACS	99.5%, min	99.99%
Assay	NF	98.0-102.0%	Pass
Identification A	NF	Infrared Absorption <197F>	Pass
Identification A	EP/BP	Boiling point : 76°C – 78°C	Pass
Identification B	EP/BP	IR comparable with Reference spectrum	Pass
Identification C	EP/BP	It gives the reaction of acetyl	Pass
Identification D	EP/BP	It gives the reaction of esters	Pass
Specific Gravity @ 25°C	NF	0.894-0.898	0.8969
Relative density @ 20°C	EP/BP	0.898 – 0.902	0.9005
Acidity	NF	NMT 0.10mL of 0.10 <u>N</u> NaOH is required The solution remains pink for not less than 15sec.	Pass
	EP/BP		Pass
Readily Carbonizable Substances	NF	No dark zone is developed within 15 minutes	Pass
Reaction with Sulfuric acid	EP/BP	Interface of the 2 liquids is not colored	Pass
Substances Darkened By Sulfuric Acid	ACS	Passes Test	Pass
Chromatographic Purity	NF	Acetaldehyde NMT 0.1% Ethyl isobutyl ether NMT 0.1% Methyl compounds NMT 0.1% Other impurities NMT 0.3%	<0.1% <0.1% <0.1% <0.3%
Color (APHA)	ACS	10 max	<10
Appearance of Solution	EP/BP	To Pass Test	Pass
Refractive Index @ 20°C	EP/BP	1.370 – 1.373	1.3727
Residue After Evaporation	ACS	0.003% max.	<0.001%
Residue on evaporation	EP/BP	30 ppm max.	<10 ppm
Limit of nonvolatile residue	NF	NMT 0.02%	<0.001%
Water	ACS	0.2% max.	0.03%
	EP/BP	0.1% max.	
Titration Acid, max	ACS	0.0009 meq/g max	<0.0001meq/g
Related substances	EP/BP	NMT 0.2% of the area of the principal peak.	Pass

Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients¹

Reported in µg/g (ppm)

Form Ethyl Acetate- ACS-USP/NF-EP-BP, Rev. 2.2, 02/18, PJM

Element	Class	Oral Concentration µg/g	Parenteral Concentration µg/g	Inhalation Concentration µg/g	TYPICAL RESULT (in µg/g) (ppm)
Cd (Cadmium)	1	0.5	0.2	0.2	0.00
Pb (Lead)	1	0.5	0.5	0.5	0.00
As (Arsenic)	1	1.5	1.5	0.2	0.00
Hg (Mercury)	1	3	0.3	0.1	0.00
Co (Cobalt)	2A	5	0.5	0.3	0.00
V (Vanadium)	2A	10	1	0.1	0.00
Ni (Nickel)	2A	20	2	0.5	0.00
Tl (Thallium)	2B	0.8	0.8	0.8	0.00
Au (Gold)	2B	10	10	0.1	0.00
Pd (Palladium)	2B	10	1	0.1	0.00
Ir (Iridium)	2B	10	1	0.1	0.00
Os (Osmium)	2B	10	1	0.1	0.00
Rh (Rhodium)	2B	10	1	0.1	0.00
Ru (Ruthenium)	2B	10	1	0.1	0.00
Se (Selenium)	2B	15	8	13	0.00
Ag (Silver)	2B	15	1	0.7	0.00
Pt (Platinum)	2B	10	1	0.1	0.00
Li (Lithium)	3	55	25	2.5	0.00
Sb (Antimony)	3	120	9	2	0.00
Ba (Barium)	3	140	70	30	0.00
Mo (Molybdenum)	3	300	150	1	0.00
Cu (Copper)	3	300	30	3	0.00
Sn (Tin)	3	600	60	6	0.00
Cr (Chromium)	3	1100	110	0.3	0.00

¹Includes all requirements for ICH Q3D-Step 4 version, EMA (EP) 5.2 and USP <232> and <233> General Chapters.

This product is for further commercial manufacturing, laboratory or research use, and may be used as an excipient or a process solvent for pharmaceutical purposes. It is not intended for use as an active ingredient in drug manufacturing nor as a medical device or disinfectant. Appropriate/legal use of this product is the responsibility of the user.